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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,997	08/29/2001	Qinwei Shi	1112-1-052CON	9957
23565	7590	11/14/2006	EXAMINER	
KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			HINES, JANA A	
			ART UNIT	PAPER NUMBER

1645

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/941,997

Applicant(s)

SHI ET AL.

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2006 and 05 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-16 is/are pending in the application.
- 4a) Of the above claim(s) 4-8 and 10-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 9 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 30, 2006 has been entered.

Amendment Entry

2. The amendment filed September 5, 2006 has been entered. The examiner acknowledges the amendments to the specification. Claims 1, 3, 9 and 16 have been amended. Claim 2 has been cancelled. Claims 4-8 and 10-15 have been withdrawn. Claims 1, 3, 9 and 16 are under consideration in this office action.

Withdrawal of Rejections

3. The following objections and rejection have been withdrawn in view of applicants' amendments:

- a) The objection of claim 3;
- b) The rejection of claims 1 and 3 under 35 U.S.C. 102(b) as being anticipated by Morjana et al., (WO97/19955);
- c) The rejection of claims 1 and 9 under 35 U.S.C. 102(b) as being anticipated by Moses et al., (WO 97/30085); and
- d) The rejection of claims 1 and 3 under 35 U.S.C. 102(e) as being anticipated by Potter et al., (WO97/39132); and
- e) The written description rejection of claims 1, 3 and 9 under 35 U.S.C. 112, first paragraph.

Response to Arguments

4. Applicant's arguments filed May 30, 2006 and September 5, 2006 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. The rejection of claim 9 under 35 U.S.C. 102(b) as being anticipated by Morjana et al., (WO97/19955) is maintained for reasons already of record.

The rejection was on the grounds that Morjana et al., teach an isolated polypeptide consisting of a N-terminal fragment of human cardiac troponin I fragment having about 95 to about 115 amino acids or to an isolated polypeptide consisting essentially of a fragment of human cardiac troponin I wherein the N-terminus of the fragment is about amino 20 to about 30 and the C-terminus of the fragment is about amino acid 95 to about 115 of native human cardiac troponin I.

Morjana et al., (WO97/19955) teach that Troponin I exists in three isoforms, one being a cardiac Troponin I isoform with an additional 31 residues on the N-terminus

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(page 2, lines 9-14). The cardiac troponin I fragment is a result of the C-terminal processing of the native cardiac troponin I molecule (page 2, lines 23-26). The resulting polypeptide has 153 amino acids (page 3-4, lines 30-1). Longer or shorter forms of this isoform can be produced by adding or deleting a few amino acids to/from the N-terminal, C-terminal or any part of the troponin I isoform (page 11, lines 30-33). Some changes in amino acids may not affect the isoforms performance (page 12, lines 5-6). The modified cDNA can give rise to the expression product for the isoform or its modified form (page 12, lines 2-4). The isolated polypeptide of claim 9 has about 115 to 135 amino acids; while Morjana teaches an isolated human cardiac troponin I fragment having 153 amino acids. Thus Morjana et al., teach an isolated polypeptide isolated meeting the limitations of claim 9.

Applicants' assert that the claimed fragments are not anticipated by or suggested by Morjana et al because of the amendments now reciting closed language. However the claims are still drawn to a polypeptide having about 115 to about 135 amino acids and it is noted that there is no definition or limitation on the "about" terminology. Therefore, Morjana et al., teach an isolated polypeptides having about 135 amino acids. Thus the rejection is maintained and applicants' assertions are not persuasive.

6. The rejection of claim 16 under 35 U.S.C. 102(e) as being anticipated by Potter et al., (WO97/39132) is maintained for reasons already of record. The rejection was on the grounds that Potter et al., teach an isolated polypeptide that corresponds to a human cardiac troponin I fragment comprised of about 95 to about 115 amino acids and SEQ ID NO:2.

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Applicants' assert that because of the amendments, the fragments of Potter et al., do not read on the instant claims. However, Potter et al., teach human cardiac troponin I that has 100% sequence homology to SEQ ID NO: 2 of the instant application. Moreover the instant claims recite transitional terms which are inclusive or open-ended and do not exclude additional, unrecited elements such as additional amino acids. Thus the teaching of Potter et al., reads on the instant claims and the rejection is maintained since applicants' argument is not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. The new matter rejection of claim 9 under 35 U.S.C. 112, first paragraph, is maintained for reasons already of record.

The rejection is on the grounds that there is no support in the specification for an isolated polypeptide consisting of a fragment of human cardiac troponin I wherein the N-terminus of the fragment is about amino 20 to about 30 and the C-terminus of the fragment is about amino acid 95 to about 115 of native human cardiac troponin I.

Applicant did not point to support in the specification for an isolated polypeptide consisting essentially of a fragment of human cardiac troponin I wherein the N-terminus

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of the fragment is about amino 20 to about 30 and the C-terminus of the fragment is about amino acid 95 to about 115 of native human cardiac troponin I. Moreover, applicant failed to specifically point to the identity or provide structural characteristics of an isolated polypeptide consisting essentially of the C-terminus fragment that is about amino acid 95 to about 115 of native human cardiac troponin I. Thus, there appears to be no teaching of that isolated polypeptide. Applicant has failed to point to pages within the instant specification or originally filed claims for support of the amendment; thus it appears that the entire specification appears to fail to recite support for the newly recited isolated polypeptide. Therefore, it appears that there is no support in the specification. Thus, applicants must specifically point to page and line number support for the identity an isolated polypeptide consisting essentially of a fragment of human cardiac troponin I wherein the N-terminus of the fragment is about amino acid 20 to about 30 and the C-terminus of the fragment is about amino acid 95 to about 115 of native human cardiac troponin I as recited. Therefore, the claim incorporates new matter and the rejection is maintained.

New Grounds of Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 9 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 1 is unclear. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, the claim is drawn to a fragment of troponin I having about 95 to about 115 amino acid wherein SEQ ID NO:2 comprises the N-terminal of human cardiac troponin I, and SEQ ID NO:2 has 99 amino acids. It is unclear how applicants are claiming a polypeptide consisting of an N-terminal fragment, wherein the fragment is longer than SEQ ID NO:2. The claim recites the broad recitation having about 95 to about 115 amino acid, and the claim also recites SEQ ID NO:2 having 99 amino acids which is the narrower statement of the range/limitation. Thus the metes and bounds of the claim cannot be ascertained by one of ordinary skill in the art and clarification is required to overcome the rejection.

b) Claim 1 recites the limitation "the N-terminal of human cardiac troponin I" in the claim. It is unclear if "the N-terminal" is referring to the N-terminal fragment of

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human cardiac troponin I or if the N-terminal is referring to something else. Therefore it appears that there is insufficient antecedent basis for the limitations of the claim or that the claim may be missing a word. However, it is noted that consistent terminology is suggested. Therefore, appropriate clarification is required to overcome the rejection.

c) Claim 9 recites the limitation "the N-terminus" and "the C-terminus" in the claim. There is insufficient antecedent basis for the limitations of the claim.

d) Claim 16 recites the limitation "The isolated polypeptide" in the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Morjana et al., (WO97/19955). The claim is drawn to an isolated polypeptide having SEQ ID NO:2.

Morjana et al., (WO97/19955) teach that Troponin I exists in three isoforms, one being a cardiac Troponin I isoform (page 2 lines 9-14). Cardiac troponin I is found in human serum and can be used in immunoassays to test for human cardiac troponin I which is valuable to the medical community (page 2 lines 15-20). The invention teaches the use of a human cardiac troponin I fragment generated from human recombinant

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troponin I (page 3, lines 32-36). Morjana et al., teach SEQ ID NO:4 which has 100% sequence homology to instantly recited SEQ ID NO: 2.

Therefore, Morjana et al., teach an isolated polypeptide isolated having SEQ ID NO:2, just as required by the instant claim.

Allowable Subject Matter

10. Claim 3 is free of the prior art.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell, can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines 
November 13, 2006